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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,197	09/27/2005	Funda Elger	K21722USWO (C038435/01913)	4609
7590 Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104			EXAMINER GREENE, IVAN A	
			ART UNIT 1619	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,197	<b>Applicant(s)</b> ELGER ET AL.	
	<b>Examiner</b> IVAN GREENE	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8 and 10-13 is/are rejected.
- 7) ☒ Claim(s) 5 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/27/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the claims***

Claims 1-13 are currently pending.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 10/11/2006 and 09/27/2005 were filed before the first office action. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. The disclosed IDS documents have been considered where in English.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The effective US filing date of the instant application has been determined to be 03/24/2004 the filing date of the PCT document PCT/EP04/03110.

### ***Objections***

The specification contains the incomprehensible phrase, "The spray-drying can effected be using conventional technology of spray-drying..." (pg. 3, lines 6 & 7). Examiner suggests the phrases should read, "The spray-drying can be accomplished by using conventional spray-drying technology..." Appropriate correction is required.

The title of the claimed invention is not descriptive. A new title that more clearly indicates the claimed invention is required. The Examiner suggests the title "Powderous Lupin Protein Formulations with Fat-Soluble Active Agent."

Claims 5 and 9 are objected to under 37 CFR 1.75(c) as being in improper multiply dependent form. Claim 5 is improper because a multiply dependent claim can only refer back in the alternative. Claim 9 is improper because a multiply dependent claim cannot depend from another multiply dependent claim (i.e. claim 5). See MPEP § 608.01(n).

### ***Claim Rejections - 35 U.S.C. 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-9, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention.
2. Regarding claim 1, and claims dependent therefrom. Claim 1 recites "--matrix of native lupin protein--" and further recites "--the protein is cross-linked--". These two phrases are seemingly mutually exclusive because, insomuch as the invention recites cross-liked, the Examiner believes the native protein to exist as a non-cross-linked protein and upon cross-linking the protein is no longer to be considered a native lupin protein. The claim is internally inconsistent for the aforementioned reason. The dependent claims 2-9 are rejected because they do nothing to correct the indefiniteness

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of claim 1.

3. Regarding claim 5, it is unclear what is meant by --mixtures of native lupin protein compositions-- as any native lupin protein composition would necessarily be a mixture of native lupin proteins.

4. Regarding claims 7, 8 and 12, the phrase "particularly" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

5. Instant claim 13 recites --if appropriate--. It is a matter of subjective interpretation what exactly the term "and if appropriate" means. The specification gives no guidance as to what would render the step appropriate. Claim 13 is rejected because it cannot be determined what exactly is meant by --if appropriate--. Furthermore, it is unclear if Applicants intend this to be an optional step.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**1. Claims 1-4, 6-8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitchett et al. (WO 1999/11143) in view of) and Perrier et al. (US Patent No. 5,912,016) and Altemueller et al. (US Patent No. 6,423,364) as evidenced by Gerrard (Trends in Food Science and Technology, 13, 2002, pgs. 391-399) and Rahman (Handbook of Food Preservation, Marcel Dekker, 1999).**

#### ***Applicants claim***

Applicants claim a stable powderous formulation comprising a cross-linked lupin protein isolate, concentrate or flour; and a fat-soluble active ingredient. Applicants further claim a method of preparing a powderous formulation comprising the steps of preparing an aqueous emulsion, adding a reducing sugar, affecting cross-linking by heating or enzymatic treatment with transglutaminase and drying the formulation to form a powder.

Examiner has interpreted recitation of claim 1, --cross-linked lupin protein--, to comprise any cross-linking that would result from heating (claim 11) or treatment with a cross-linking enzyme (claim 12).

#### **Determination of the scope and content of the prior art (MPEP 2141.01)**

Fitchett et al. teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) are widely

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used in the food industry (pg. 1, lines 9-15). Fitchett et al. further teaches, "Lupins have long been recognized as a viable alternative to soya as a source of vegetable protein for human consumption" (pg. 2, line 7). Fitchett et al. further teaches, "It has long been known that the protein content of lupin seeds is equal to that of whole soya beans, and it has been exploited for years as a sources of (non-functional) protein in animal feeds" (pg. 2, lines 12-14). Fitchett et al. further teaches "lupin concentrates and isolates per se are known...and theses isolates/concentrates are also known to affect the chemical/physical behavior of foodstuffs in which they are incorporated" (pg. 2, lines 15-17).

Fitchett et al. teaches an emulsion comprising lupin protein composition, water and fat (pg. 2, line 35), where the emulsion may contain any suitable ratio of protein composition, water and fat (pg. 3, line 1). Fitchett notes that by "fat" is meant fats which are liquid at room temperature and, "often referred to as oils" (pg. 2, line 38 & pg. 3, line 1). Fitchett further teaches the example wherein palm fat is used (pg. 3, line 28). Fitchett et al. further teaches, the lupin protein is preferably present in substantially native form which is associated with higher functionality (pg. 4, lines 10-12). Fitchett et al. further teaches the examples of products covered by the invention including a fat-filled powder (pg. 4, lines 32-33). Fitchett et al. further teaches, "It may be desirable to derivatize or physically modify the lupin protein, for example...denaturing the proteins...by heating...or by partial...enzymatic digestion" (pg. 6, lines 8-10).

#### **Ascertainment of the difference between the prior art and the claims**

**(MPEP 2141.02)**

The difference between the rejected claims and Fitchett et al. is that Fitchett et al. does not expressly teach cross-linking the lupin protein nor a specific fat-soluble active ingredient of neither claim 6 nor a process for preparing a powder formulation. The deficiency in cross-linking the lupin protein and a fat-soluble ingredient is cured by Perrier et al.; and the deficiency in powdered formulation is cured by Altemueller et al. Rahman provides motivation for producing a powder formulation and Gerrard teaches the chemistry of protein-protein crosslinking including Maillard and transglutaminase initiated cross-linking.

Perrier et al. teaches particles of cross-linked plant proteins (title) wherein the particles "...encapsulate substances, particularly active principles, including lipophilic active principles such as vegetable, mineral or synthetic oil, vitamin A and vitamin E derivatives..." (col. 8, lines 38-41). Perrier et al. further teaches it is well known in the art that encapsulation of active ingredients has the advantages of protecting the ingredients as well as controlling the release rate at the site of use (col. 1, lines 12-15). Perrier et al. further teaches the example in which microcapsules with a wall formed of crosslinked lupin proteins is made by dissolving sweet white lupin flour in water containing a succinate buffer of pH=6, the mixture is heated, the supernatant is separated, glucose is added emulsification and crosslinking are then carried out (example 9).

Altemueller et al. teaches a novel functional food ingredient comprising an unrefined plant protein material wherein the functional food ingredient is hydrated, partially denatured and dried (abstract). Altemueller et al. further teaches, "The plant



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protein material may be any unrefined protein material derived from a plant...Representative...examples of such plant protein materials include...lupin protein containing materials..." (col. 5 line 67, col. 6 lines 1 & 3-5). Altemueller et al. further teaches drying of the processed plant protein material, "The flash vaporized unrefined soy protein material slurry may be spray-dried to produce the dry unrefined soy protein material food ingredient of the present invention" (col. 26, lines 33-35).

Rahman gives several motivations for producing a powder formulation including, "...to increase shelf life, reduce packaging and storage costs, lower shipping weights, improve sensory attributes, encapsulate flavors, and preserve nutritional value in some cases" (pg. 173, paragraph 3).

Gerrard teaches protein-protein crosslinking in food (title) which comprises formation of covalent bonds between polypeptide chains within a protein or between proteins (pg. 391, col. 2, lines 24-27). Gerrard further teaches, "Food processing often involves high temperatures, extremes in pH, particularly alkaline, and exposure to oxidizing conditions and uncontrolled enzyme chemistry. Such conditions result in the introduction of protein crosslinks, producing substantial changes in the structure of proteins, and therefore the functional and nutritional properties of the final product." (pg. 391, col. 2, lines 38-45). Gerrard further teaches different types of crosslinking including, disulfide crosslinks (pg. 392) crosslinks derived from the Maillard reaction (heat initiated) and crosslinks formed via the enzyme transglutaminase (also see Figures 1 & 2).

### **Finding of prima facie obviousness**

#### **Rationale and Motivation (MPEP 2142-2143)**

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Fitchett et al. with the teachings of Perrier et al. and Altemueller et al. because they each teach plant protein compositions for use in food products. The processing of foods, which is common place in modern society, provides for an increased shelf life, consistent and appealing texture, and enhanced flavor. Cross-linking of proteins provides a means for controlling the functional properties of foods, such as the texture. A cross-linked protein can also provide a matrix for additional beneficial ingredients such as fat-soluble vitamins. A dry powdered product would be very desirable for functional proteins for use as food additives because the storage conditions would be more favorable and the shipping costs would be reduced. It would have been prima facie obvious at the time of the claimed invention that a cross-linked protein would provide for an enhanced food additive. It would have been prima facie obvious that vitamin enrichment would provide for a more nutritious and therefore desirable product. It would have been prima facie obvious at the time of the claimed invention to produce a powder formulation from the emulsion taught by Perrier et al. because, as suggested by Rahman, the shelf life would increase and the shipping costs would decrease adding value to the product. Furthermore, it is prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a plant protein powder. See MPEP 2144.06.

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A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success, for example the prior art teaches cross-linking of different proteins using various methods, as discussed above. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Nonstatutory Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**1. Claims 1, 6-9, 11 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 12-14, 16 and 17 of copending Application No. 10/564,635 (hereafter referred to as '635) in view of Bewert et al.**

Instant claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of native lupin protein composition wherein the protein is cross-linked; instant claim 11 recites, a process wherein a reducing sugar is added and the composition is submitted cross-linking by heating. Copending '635 claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of milk protein compositions, wherein the protein is thermally cross-linked with a reducing-sugar. The difference between the claim of copending '635 and instant claims 1 and 11 is the primary cross-linking protein. Copending '635 claims 6 recites the formulation additionally comprises a plant protein and copending '635 claim 8 recites formulations which further comprise plant protein which is obtained from potato protein, soy protein, wheat protein, pea protein, rice protein or lupin protein.

Instant claim 6 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or carotenoids, or a polyunsaturated fatty acid; instant claim 7 recites form formulations wherein the fat-soluble active ingredient is mixed with a plant

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or animal fat. Copending '635 claim 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; copending '635 claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Instant claims 6 and 7 are coextensive in scope with copending '635 claims 12 and 13.

Instant claim 8 recites formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Copending '635 claim 14 recites, formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Instant claim 8 is coextensive in scope with copending '635 claim 14.

Instant claim 13 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the native lupin protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein by heat treatment or by treatment with a cross-linking enzyme. Copending '197 claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein with heat treatment. The difference between instant claim 13 and copending '635 claim 17 is the primary cross-linking protein and the alternative possibility of enzymatic cross-linking instant claim 13.

The difference between Copending '635 and the instant claimed invention is that copending '635 does not explicitly teach the use of lupin protein for the primary cross-

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linking protein. The deficiency of using a lupin protein is cured by the teachings of Perrier et al., which teaches particles of cross-linked lupin plant proteins wherein the particles encapsulate active substances, including lipophilic active principles, as discussed above.

It would have been prima facie obvious to combine copending '635 with the teachings of Perrier et al. and produce the instant claimed invention because both applications teach cross-linked protein food additives with a fat-soluble active ingredient in the protein matrix. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a cross-linked protein food additive. See MPEP 2144.06. Furthermore, the lupin protein of Perrier et al. would provide an added nutritive value to copending '635 and produce a more desirable product. It would be obvious to substitute the milk protein of '635 with the lupin protein of the instant application because it would provide access to a new market of consumers for which the milk protein would be unacceptable (e. g. vegans). Examiner notes the comprising language of the instant application invites additional ingredients.

This is a provisional obviousness-type double patenting rejection.

### ***Conclusion***

Claims 1-13 are pending. The specification is objected, as are claim 5 and 9. Claims 1-9, 12 and 13 are rejected under 35 USC § 112. Claims 1-4, 6-8 and 10-13 are

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rejected under 35 USC § 103(a). Claims 1, 6-9, 11 and 13 are rejected on the grounds of nonstatutory double patenting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached Monday thru Thursday 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1616

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/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616